EXHIBIT C

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO: *Wave 11 Cases*	

GENERAL TVT TVT-O TVT-EXACT TVT-ABBREVO EXPERT REPORT OF CHARLES R. HANES, II, MD, FACOG, FPMRS

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REGARDING ETHICON'S MIDURETHRAL SLING PRODUCTS

My Background

I attended Vanderbilt University, majored in biology, and earned a BA degree in 1967. I attended medical school at Tulane University in New Orleans and earned an MD degree in 1971. I returned to Vanderbilt and spent two years in the general surgery residency program.

From 1973-1975, my postdoctoral education was interrupted by a military obligation. In 1973, I was stationed in the U.S. Army medical corps as a battalion surgeon with the 1st battalion, 81st field artillery regiment at Wiley Barracks in Neu Ulm, Germany. In 1974, I was transferred to Camp Darby in Tirrenia, Italy where I functioned as a partially trained surgeon in the U.S. Army hospital.

In 1975, I returned to complete my residency training in the specialty of Obstetrics and Gynecology at Emory School of Medicine in Atlanta, Georgia. During this time, I had the good privilege of working under some of the most outstanding vaginal surgeons in the country. Dr. John D. Thompson was the chairman of the department. Dr. Cullen Richardson and Dr. John Ridley were both on the clinical faculty. I operated with all three of these men and learned much of what I know based on that experience. I completed my residency training in 1978 and have been engaged in the private practice of medicine since then. I moved to Mobile, Alabama in 1979 and have been in practice continuously ever since.

For approximately 24 years, I functioned as a generalist in ObGyn. I stopped obstetrics in 2002 and began to focus my gynecologic practice on urogynecology. At the time, there was very little formal training in the subspecialty. I attended numerous meetings and spent time with many of the leaders in the field, attending courses and spending time in their operating suites observing surgery.

In 2006, I left the group that I was affiliated with so that I could limit my practice exclusively to urogynecology and be able to build a referral-based practice with other ObGyn groups in the area.

In 2011, the American Board of Medical Specialties (ABMS) officially recognized Female Medicine and Pelvic Reconstructive Surgery as a subspecialty. In so doing they acknowledged that a specific skill set is needed for the successful treatment of women who have pelvic floor disorders. These fall primarily under the category of incontinence and pelvic organ prolapse (POP). A board certification examination was offered for the first time in 2013. I sat for and passed the board exam in that first year.

In 2017, I relocated my practice to the University of South Alabama health care system. I am a full-time employee of the university. I spend 75% of my time in private practice and 25% teaching medical students and ObGyn residents. One aspect of my teaching responsibility is to train residents on midurethral slings (MUS). This involves teaching the indications for surgery, the technique of implantation, and the management of postoperative care and complications. For the most part, these fall into the category of vaginal pain, dyspareunia, mesh erosions, and voiding problems.

In the course of my career, prior to the introduction of synthetic mesh midurethral slings, I performed over one hundred Burch procedures for the treatment of SUI. After 1998 and the availability of MUS, I have performed over 1,000 MUS procedures. Approximately2/3s of these have involved the transobturator approach (TVT-O, TVT Abbrevo) and 1/3 the retropubic approach (TVT and TVT Exact). In addition to this, I have accumulated vast experience in treating complications of MUS as well as other mesh products used for the correction of prolapse.

In the course of preparing my opinions for this report, I have reviewed medical literature, incorporated my own professional experience. I have also reviewed numerous Ethicon documents to include the TVT family of products' IFUs, professional education materials and the 2000 Surgeon's Monograph. A list of materials that I may use in future trials is attached to this report. I've also read reports from various Plaintiffs' experts and considered the materials cited therein.

All my opinions are held to a reasonable degree of scientific and medical certainty. In short, I believe that TVT, TVT-O, TVT Abbrevo and TVT Exact were safe and effective, state of the art products for the repair of stress urinary incontinence. They were not defectively designed. These products provided superior efficacy compared to other surgical repairs like Burch or pubovaginal slings and presented an acceptable risk/benefit profile with low rates of complications to include mesh exposure, dyspareunia, pain, scarring and urinary problems. Ethicon adequately warned of the risks of TVT, TVT-O, TVT Abbrevo and TVT Exact in its IFUs and provided additional materials in its professional education materials and the 2000 Surgeon's Monograph. Regardless, all of the complications associated with the use of TVT, TVT-O, TVT Abbrevo and TVT Exact were basic risks of any vaginal SUI repair and were commonly known by pelvic surgeons at the time TVT was first sold in 1998. All of my opinions in this report are based upon my ongoing review of the medical literature, my education, training, experience and collaborations with colleagues.

My Testimonial History

I have been deposed as an expert witness on two cases:
Noles v. Ethicon and Aldridge v. Ethicon.

I charge $450.00 per hour for legal consulting and $5000 per day for court appearances.

My Experience Treating Female Stress Urinary Incontinence

I was trained to treat female urinary incontinence in my residency. At the time, the retropubic urethropexy procedures were considered to be the "gold standard." The original prototype was referred to as the Marshall-Marchetti-Krantz (MMK) operation. A modification, referred to as the Burch procedure, was developed and was the procedure that I routinely performed for treating stress incontinence. Both of these operations shared a common feature: they elevate and support the bladder neck.

The theory at the time was that female stress urinary incontinence developed because the bladder neck and upper urethra had descended out of the high-pressure zone of the abdomen into the low-pressure zone of the vagina. Stress incontinence resulted due to the loss of this pressure differential at the proximal urethra resulting in insufficient intraurethral pressure to maintain continence. The retropubic urethropexies were designed to elevate the proximal urethra back into the higher-pressure zone.

The other popular operation for the treatment of stress urinary incontinence at the time was anterior colporrhaphy. This operation was designed to correct prolapse of the anterior vagina and bladder that often accompany stress incontinence. It consists of identifying, reapproximating, and tightening the fascial remnants within the anterior vaginal wall that had been torn or stretched during the stress and trauma of childbirth as well as other sources of pelvic organ trauma. When incontinence coexisted with the anterior vaginal prolapse (cystocele), extra support and elevation of the bladder neck was achieved by placing a suture between the pubourethral ligaments at the proximal urethra. As with the urethropexies, the objective of this stitch was to elevate the proximal urethra back into the high-pressure zone. In reality, it also constricted and partially obstructed the urethra.

A third operation that could be offered was the pubovaginal sling. This was a much more invasive operation and was usually reserved for patients who had failed previous operative attempts. I was not trained to do that operation during my residency but have done several during my private practice.

In the 1990's, some practitioners began using various synthetic materials in the surgical correction of pelvic organ prolapse and urinary incontinence. Based on the extensive work and experience of Dr. Ulmsten, the first tension-free midurethral sling was introduced by Ethicon in 1998. This was referred to as the TVT or tension-free vaginal tape. This truly revolutionized not only the treatment but also the understanding of the underlying mechanism of stress urinary incontinence.

Although there were other incontinence procedures that I have not yet mentioned, the most effective MMK and Burch procedures were performed through open abdominal incisions. The laparoscopic approach had also been developed, but this required a skill set that most general ObGyns lacked. With the TVT, a much more morbid, invasive procedure was being replaced by a simple, outpatient operation that could be accomplished through a 1.5 centimeter vaginal incision.

No longer was the objective of the surgery to elevate the proximal urethra but rather to support the midurethra. This alteration in the philosophy and understanding of the biomechanics of incontinence evolved into what has become known as the integral theory. It is based on early work done by Dr. Ulmsten and Dr. Petros. They became convinced that the dominant theory about the mechanism of urinary continence was incorrect.

The integral theory maintains that continence depends on a dynamic relationship between the pubourethral ligaments that provide support at the midurethral level, the levator ani muscles of the pelvic floor, and the anterior vaginal wall. Based on this theory, the goal of surgery became to support the midurethral, the same level of

support formerly provided by the pubourethral ligaments that had become weakened or damaged.

Prior to the TVT, all operations created a static support at the proximal urethra and bladder neck and were frequently complicated by urinary retention and dysfunctional voiding problems. With the advent of this new understanding, the goal was to simply create a platform in the anterior vaginal wall that would effectively support the urethra and against which the urethra would be compressed during the descent associated with increased abdominal pressure.

I became an early adopter of the TVT based on the extensive studies of Dr. Ulmsten and his European colleagues as well as the voluminous experience they had accumulated. Although the TVT was not introduced into the United States until 1998, Dr. Ulmsten had done many cases with the original prototype referred to as intravaginal slingplasty, and he had begun publishing his results as early as 1996.

Initially, as soon as I became satisfied that the chances of causing harm were negligible, I could not refrain from offering this minimally invasive procedure. The claims of efficacy were impressive but still needed to be substantiated by well-designed studies, many of which were already in process. Furthermore, if the TVT failed, one of the more invasive urethropexies could still be performed with the patient having only undergone previous minor surgery. This line of reasoning compelled me to offer the TVT to my patients. I encountered no one who hesitated to consent for it. Quickly, my favorable impression was reinforced by the reports I received from an almost universally happy group of patients. Within a very short period of time, other reports and studies corroborated my experience.

The transobturator TVT (TVT-O) was introduced in 2004 and was followed by a modification, the TVT Abbrevo in 2010. Both of these were introduced through the same midurethral incision, but rather than being passed behind the pubic bone and emerging through two puncture sites in the skin just above the pubic bone on either

side of the midline, they passed laterally traversing the obturator foramen and emerging at the crease in the groin between the thigh and the vulva. I embraced these products because of certain qualities that I considered advantageous and upon which I will further elucidate later in this report.

In 1998, I became a preceptor for Gynecare, the subsidiary of J&J and Ethicon that produced and marketed products for pelvic floor surgery and incontinence. Between 1998 and 2012, I taught hundreds of physicians how to perform the TVT and later, the TVT-O and TVT Abbrevo. In my instruction, I provided a cadaver lab experience through the University of South Alabama's department of anatomy. In this setting preceptees could actually perform the procedure on a cadaveric specimen, see, and understand the anatomical relationships between the TVT trocars and mesh and the surrounding structures.

Following the lab, they accompanied me into the operating suite to watch live surgical procedures. This experience was further supported by reviewing the instructions for use (IFU) as well as a discussion of potential complications and how to handle them should any arise. During these professional education sessions, we would discuss the various different potential complications that can follow implantation of a MUS, such as infection, pain and dyspareunia. It's important to note that all of these complications are also associated with any other vaginal surgeries. Mesh erosion/exposure was also discussed as was the most effective ways to treat or manage this potential complications. It's also important to note that as pelvic floor surgeons, we have long been familiar with potential complications associated with suture erosions, which can happen following any vaginal surgery (Yazdany 2010; Toglia 2008; Luck 2005).

During these years that I served as a preceptor, I also attended meetings in other cities designed to educate other general ObGyn physicians about the midurethral sling (MUS) products. In addition, I attended a summit meeting hosted by Gynecare every year for all of the preceptors around the country. These were always

extremely helpful because it provided a unique opportunity to focus with all of the thought leaders in the field on one subject. I was always impressed with the way Gynecare conducted these events. They provided the venue and opened the floor for the physicians to discuss anything and everything regarding the treatment of stress urinary incontinence (SUI) and any potential complications that might follow a MUS surgery.

I stopped serving as a preceptor for Ethicon in 2012. By this point, almost all residency training programs in the US were teaching MUS. Within fourteen years, Ethicon's prototypical TVT, followed by many other MUS products from many other companies, can be credited for transforming the treatment of SUI on a national scale.

I continue using the MUS for surgical correction of SUI. I have performed well over a thousand of these operations and still average doing at least two every week. Between 1998 and 2005, I used the TVT almost exclusively for SUI; however I still offered the Burch procedure. After the introduction of the TVT-O, it became my product of choice and later the TVT Abbrevo. I also did many periurethral bulking procedures on select patients who did not have hypermobility of the bladder neck, but I no longer do the bulking because I have found that the retropubic TVT works well on these patients, many of whom have intrinsic sphincter deficiency.

I also use the TVT Exact, which is an enhanced version of the original retropubic TVT. I prefer the retropubic approach in patients who have intrinsic sphincter deficiency and in patients who have had a previous transobturator sling that either failed or had to be removed. It—and the other TVT products I've used—have proven to be safe and effective surgeries in my hands.

<u>What Is Stress Urinary Incontinence And Why Is It Such A Problem?</u>

SUI is the involuntary loss of urine preceded or accompanied by an increase in abdominal pressure such as occurs with a cough or sneeze. As the severity of the

disorder increases, less pressure is required to elicit leakage such that fast walking or even the slight strain to stand up from a sitting position may trigger the loss of urine.

Female SUI is very common effecting as many as 33% of all women. Almost half of these are troubled enough to make the decision to undergo surgery for correction (Wu, 2014). 13.6% of women will have a surgical procedure to correct urinary incontinence during their lifetime (Wu 2014). Although there are other unusual causes of incontinence such as fistulas between the bladder and vagina and overflow incontinence due to neurogenic bladder disorders, the large majority of cases are due to either stress urinary incontinence (SUI), urge incontinence also referred to as overactive bladder (OAB), or a combination of these referred to as mixed urinary incontinence (MUI).

There are two varieties of SUI. The more common type occurs because of a lack of adequate support of the urethra resulting in the finding on physical exam of hypermobility of the bladder neck in which the examiner can visualize descent of the distal anterior vagina under the urethra as the patient is asked to cough or strain down.

The less common variety occurs when the sphincter mechanism that encircles the urethra is weak. This is referred to as intrinsic sphincter deficiency (ISD) and usually results in a more severe degree of incontinence.

OAB or urge incontinence, on the other hand, results when the bladder muscle contracts involuntarily and cannot be willfully suppressed. This results in leakage that is generally much more severe than the leakage of SUI. Treatment of OAB is primarily nonsurgical.

Many women have a combination of these two, MUI. They may require both pharmacologic treatment for the OAB as well as surgery for the SUI.

Although urinary incontinence is never a life-threatening condition, it is a major factor in one's quality of life. Many women suffer from depression and anxiety and there is also a significant economic impact as the purchase of absorbent products can require a significant sum of money in the course of a year, none of which is covered by insurance. Studies by Fantl (1996) and Hu (2004) determined the total health care dollars spent annually on urinary incontinence exceeds 20 billion dollars. Moreover, SUI often has an adverse effect on a woman's sexual quality of life and can hinder their physical and social activities due to a constant fear of leakage.

In many cases, women are forced to remain house-bound because of the constant threat of accidents and embarrassment. Often times, the elderly become increasingly immobile from arthritis and this further compounds the issue when they cannot get to a bathroom quickly. As a result, urinary incontinence is a common factor in the decision making process of seeking assisted living or nursing home facilities.

The major risk factors for the development of SUI are vaginal delivery and hysterectomy. In both cases, there is a possibility that the support structure of the anterior vaginal wall and urethra may be weakened. Often, if this occurs, it is not immediately apparent to the patient because the weakening is not sufficient to cause SUI or it may be so insignificant that it does not create a significant bother. Over the passage of time, the incontinence may gradually worsen with the stresses of physical activity, weight gain, as well as the natural weakening of tissues during the aging process.

Other contributory factors are obesity, strenuous physical activity that is accompanied by abdominal muscle straining, smoking, chronic coughing and chronic constipation. Less common are activities associated with abnormal and extreme pressure on the pelvic floor such as jumping on a trampoline or skydiving.

How Is SUI Treated?

There have been many treatments for SUI. For purposes of this discussion, I will consider them in two categories; non-surgical and surgical. Furthermore, I will limit the surgical procedures to those that have been most popular during my practice career.

The non-surgical treatment for SUI is devoted to behavior modification and strengthening the pelvic floor muscles. With behavior modification, the patient is instructed to avoid allowing her bladder to become too full. With scheduled voiding, filling is limited and, as a result, when a sneeze occurs, it is less likely to result in leakage of a significant amount. Also, there are maneuvers that she may be taught when she anticipates a cough or sneeze such as voluntarily tightening the pelvic floor or sitting down.

Kegel exercise is voluntarily contracting the pelvic floor muscles. This often must be taught since it is difficult to identify and isolate these muscles from other muscles within the pelvis. Physical therapy can be very helpful with a therapist who is knowledgeable in this specialized area. There are also a number of devices that may be used to provide feedback to the patient so that she may know that she is isolating and contracting these muscles appropriately.

Patients who are highly motivated and diligent to incorporate these non-surgical modalities will achieve benefit, often decreasing the severity of their incontinence. It is unusual, however, that they can be totally cured of their SUI, and they will frequently resort to surgery.

Another non-surgical treatment is the use of vaginal pessaries. These are devices inserted into the vagina and can be thought of as a vaginal splint. The long-term use

of a pessary is unusual. Most women, over time, find them to be inconvenient and cumbersome. In addition, they frequently cause a vaginal discharge.

Needle urethropexies were popular surgical procedures in the eighties and nineties. There were numerous minor variations, each bearing the name of its inventor. They all had the same mechanism of action. A small incision was made in the anterior vagina and the bladder neck was identified at its juncture with the urethra. Another incision was made in the abdominal wall above the pubic bone. The space between the pubic bone and the bladder was identified and a needle passed down to the vaginal incision on each side of the urethra. A suture was then retrieved as this needle was withdrawn. These sutures served to elevate and support the proximal urethra. Short-term success with these operations was often quite good but, with time, the success decreased significantly resulting in recurrent SUI. Bladder perforations were not uncommon although these did not represent a significant risk because they were self-sealing due to the small caliber of the needle used.

Anterior colporrhaphy with a Kelley-Kennedy plication suture at the level of the proximal urethra was also commonly performed in association with cystocele repair. This frequently succeeded in the short-term relief of SUI, but it rarely provided a long-term solution.

The MMK was popularized by Dr. Kermit Krantz. This operation was performed through an open abdominal incision. The space between the pubic bone and the bladder was developed and the junction of the urethra with the bladder neck was identified. Permanent sutures were passed through the fascia on both sides of and underlying the urethra. These were then secured to the periosteum on the back surface of the pubic bone thereby elevating the proximal urethra.

The Burch modification of this placed the sutures within the same fascial layer on each side of the urethra at the bladder neck but secured them to Cooper's ligament on the pelvic bone. This was technically easier to perform and, between these two,

became the operation of choice. In a study comparing the Kelly-Kennedy plication, needle suspension, and the Burch procedures success rates at five years were 37%, 43%, and 82% respectively (Bergman 1995). Because of its clear superiority shown by this and other studies, the Burch retropubic urethropexy became known as the "gold standard" for the surgical correction of SUI.

The pubovaginal sling (PVS), also referred to as an autologous fascial sling, was resorted to in the mid-nineties for severe cases of SUI. It is still used today for certain limited indications. This operation is similar to the needle procedures but, instead of a suture to elevate the bladder neck, a strip of fascia is used. This may be harvested from the patient (autologous) or from a cadaver (homologous). The fascia passes under the proximal urethra and both ends are then secured to the abdominal wall muscles. Unlike the needle operations, the PVS has good long-term results.

Periurethral bulking procedures use any of a variety of materials to create bulk around the urethra. The material is injected by needle through the inner surface of the urethra so that, by virtue of its bulk, helps to narrow the urethral inner lumen, thereby enabling the sphincter mechanism to keep the urethral lumen closed. These procedures rarely are associated with long-term success when used solely for correction of SUI, but they can prove beneficial to enhance the outcome of a patient who has achieved a suboptimal outcome form a sling procedure.

As mentioned, the midurethral sling procedures have become very popular replacing the Burch procedure as the widely recognized "gold standard" operation for the surgical correction of SUI (Serati 2009).

Midurethral Sling (MUS)

Although the TVT shares certain features with both the needle urethropexy and the pubovaginal sling, it also differs in several important and dramatic ways. As with the needle procedures, there is minimal dissection since a large diameter needle or trocar is used to pass the sling blindly through the retropubic space. In contrast,

however, the sling is positioned at the middle of the urethra and not at the bladder neck, a critical deviation from all forerunners.

In addition, the sling is not secured to any structure, hence the name tension free vaginal tape. The synthetic mesh used for these procedures is designed to hold in place initially by a phenomenon commonly referred to as the "Velcro" effect. Because of the large pore size within the mesh, tissue collapses into these pores after removal of the protective plastic sheath and enables the sling to remain stable until tissue ingrowth occurs over the ensuing several weeks. This tension free feature provides an important distinction from the other urethropexy procedures (MMK, Burch, PVS, and needle slings). No longer is the urethra elevated into a fixed position, but with the MUS, it is simply supported. This becomes an important feature in minimizing many of the complications that the other procedures experienced.

The third significant deviation from all other surgical incontinence operations is that the TVT, as well as the other Ethicon products, use synthetic polypropylene mesh. This was not the first operation to use polypropylene mesh. In fact, it had been used and reported on by Dr. Usher for the repair of abdominal hernias since the 1970's. However, this was the first time that it was used routinely in any form of vaginal surgery.

One of the major attractions of the TVT is its simplicity and ease of insertion. As a result, it is very reproducible and associated with a short learning curve. I will briefly describe the technique of both the TVT and the TVT-O (TVT Abbrevo).

The surgery may be performed with general, regional, or local anesthesia. I prefer the combination of local anesthesia and light sedation since I can ask the patient after insertion to cough and/or bear down which facilitates accurate tensioning and helps to prevent over-tensioning.

A catheter is placed in the bladder. After establishing appropriate anesthesia, the tissues under the urethra are perfused with a local anesthetic agent. This helps relieve postoperative discomfort and, more importantly, it creates more space below the urethra. That, in turn, makes it less likely that the urethra might inadvertently be injured in the process.

At this point, a 1 to 1.5 centimeter incision is made in the vaginal wall at the level of the midurethral. Narrow tunnels are then created from this incision on either side of the urethra to the inferior margin of the pubic bone (TVT) or laterally to the inside margin of the inferior pubic ramus (TVT-O). The two trocar devices, with the sling attached between them, are then passed through these tunnels and curve up in their trajectory remaining close to the back side of the pubic bone and away from the bladder to exit through two puncture sites in the abdominal skin above the pubic bone (TVT) or behind the inferior pubic ramus, curving through the obturator foramen to exit through small puncture sites in the leg crease in each groin (TVT-O).

The tension of the sling is adjusted. Cystoscopy is performed to make certain that the bladder or urethra was not damaged inadvertently, and closure of the vaginal incision is performed with suture. The exit sites in the skin are so small that tissue glue is normally all that is necessary for them.

While briefly describing this, I realize that the entire procedure is routinely performed in less time than it took for me to write about it in these last few paragraphs. The patient is routinely discharged from the recovery room after voiding and making certain that she is able to adequately empty her bladder. Using the local and sedation technique, it is not unusual for her to be discharged within an hour of the procedure. Postoperatively, she is instructed to refrain from sexual intercourse for several weeks and to avoid any heavy lifting or straining. Most patients are able to resume all other routine activities on the day following surgery and rarely require narcotic analgesics for longer than the first day.

How Effective Is TVT And How Does This Compare With Other SUI Procedures?

Prior to the introduction of TVT, there was very little data from well-designed studies regarding the safety and efficacy of incontinence procedures. After its introduction, the TVT has become the most thoroughly studied procedure in the entire surgical literature both gynecologic and other. Over 2,000 articles have been published in the scientific literature. Many of these have been randomized controlled trials comparing TVT and/or TVT-O with other incontinence procedures. These studies form the basis on which many professional organizations have based endorsements of the MUS procedures regarding both their effectiveness and their safety. I will touch on some of the highlights.

MMK, Burch, and PVS procedures were widely recognized as the best operations for SUI prior to MUS. Although they had good short-term success rates, they also had high complication rates. They involved major surgery with large abdominal incisions. In 1985, Stanton published a paper stating that they were associated with a significant risk of wound complications, bleeding, and urinary tract injuries. A meta-analysis performed by SGS in 2014 reported that with all of these operations, operating times are often in excess of 2 hours and catheter drainage of the bladder is usually required for several days. Several authors have reported an incidence of voiding dysfunction up to 25% (Erikesen 1990). This difficulty in voiding is thought to be related to the fixed position of the urethra in contrast with the MUS procedures.

Aside from the increased risk of complications of these forerunner operations, their success rates did not last over time. Dr. Richter reported in the SISTEr trial (2011), based on the results of 655 women, that success of the PVS was 66% at 2 years, 34% at 5 years, and 27% at 7 years. In comparison, the Burch patients did worse; 49% at 2 years, 24% at 5 years, and 13% at 7 years. This was a shocking revelation given the fact that the Burch had been considered the "gold standard."

In a 2011 Cochrane review of 62 randomized controlled trials totaling 7101 women comparing the traditional urethropexy procedures with MUS, Ogah reported that the TVT was just as effective as the PVS procedure; however, the TVT had shorter operating times and less voiding dysfunction postoperatively. Compared with the Burch, MUS was as effective but had fewer operative complications, less voiding dysfunction, and shorter operating time but that the rate of bladder perforations was higher. These results are not unique (Ward 2002 and 2008; Novara 2010).

A systematic review and meta-analysis conducted by the Society of Gynecologic Surgeons (SGS) found, when comparing MUS with PVS, that the subjective cure rate of PVS was 50% lower than that with MUS (Schimpf 2014). This is very significant because regardless of how effective an operation is from the surgeons and the researcher's point of view, the more important determinant of success is how it is regarded by the patient.

An unexpected benefit of the MUS procedures is their effectiveness in the treatment of MUI. Neither the Burch nor the PVS had ever proven to demonstrate a beneficial effect regarding the OAB component of MUI. Several studies have shown conclusive evidence that MUS cured many of these difficult cases (Tahseen, 2009; Jain, 2011).

Techniques have been developed that enable the Burch procedure to be performed laparoscopically, thereby eliminating some of the morbidity associated with a large abdominal incision. Apart from the fact that this technique is difficult to learn and become proficient at, a randomized trial comparing the TVT and laparoscopic Burch, reported objective cure was significantly higher with TVT (94% v. 78%) (Valoas, 2014). Other studies have found similar results (Jelovsek 2008). Moreover, laparoscopic Burch procedures have been shown to have lower success rates than open Burch surgeries (Siddighi 2004). Other studies have shown an inability to demonstrate the superiority of laparoscopic Burch compared to open Burch (Lapitan 2012).

Long-term studies have followed patients over a protracted period of time and have found that the TVT has lasting benefit. Nilsson followed a cohort of 90 women for 11 years. Subjective cure was 77% while 90% had no objective evidence of SUI (Nilsson 2008). He reported on the same group of women in 2013, representing an average postoperative interval of 17.5 years. 87% of them remained either subjectively cured or significantly improved.

Karmaker reported on 170 patients who had transobturator MUS procedures. 9 years following surgery, they reported subjective success as 71.6% and another 14% reported improvement. 76.8% reported significant improvement in quality of life. Mesh exposure was encountered in 4.5%. (Karmaker, 2017)

In the longest follow up reported, Bakas reported subjective and objective cure rates of 78.6% and 83.9% respectively on 57 patients 17 years following their MUS. There was only one mesh exposure (1.75%). (Bakas, 2018). Braga reported similar results in his 17 year follow-up study (2018). By contrast, long term efficacy of the Burch is inferior to that of TVT and TVT-O. For example, in one study, 56% of Burch patients subjectively experienced significant urinary incontinence (Kjolhede 2005). Other studies have found high rates of recurrent incontinence (Albo 2007; Demirci 2001; Alcalay 1995).

In a retrospective cohort study reported in JAMA 95,057 women were followed for a median time of 5.5 years Almost two-thirds of them had a retropubic sling with the remainder having a transobturator sling. The risk of any complication requiring mesh removal was 3.3% at 9 years. (Gurol-Urganci, 2018)

Dozens of long term studies (greater than five years) have evaluated both the safety and efficacy of TVT and TVT-O and have concluded that both products are safe and effective even at long term follow-up. The rate of long-term complications is low, to include groin pain in TVT-O studies. Moreover, despite plaintiffs' experts criticisms of the original Ulmsten study which was followed up at 17 years by Nilsson, the

weight of long term data that exists now demonstrates the soundness of the original Ulmsten study. Regardless of whether a study was conducted by someone with a financial connection to Ethicon or not, the vast majority of them conclude the same thing: that TVT and TVT-O is safe and effective both in the short and long term.

There are over 100 randomized controlled trials comparing TVT and TVT-O with other operations. In addition, there have been several Cochrane reviews, systematic reviews, meta-analyses, and practice guidelines (Ogah 2009, Rehman 2019, Ogah 2011, Lapitan 2013, Novara 2010, Dmochowski 2010, Schimpf 2014, Cochrane 2015). Of note these reviews have consistently found a relatively low erosion/exposure rate of 1 to 3 percent. Most recently, the Cochrane Review again assessed the safety and efficacy of MUSs (Ford 2019). They concluded:

> MUS has good rates of subjective cure in the short and into the longer term. The overall rates of complications are low including those associated with the use of mesh implants. When compared to other continence procedures, MUS is equally effective in regard to cure but has lower rates of complications and more favorable operative outcomes. The use of mesh has been supported by major Urogynaecological Societies along with the reports from government driven enquiries into the use of mesh.
> **Conclusions**: Overall, MUS have been shown to be an effective and safe surgical treatment for management of stress urinary incontinence.

How Safe Is TVT And How Does This Compare With Other SUI Procedures?

All operations, no matter how minor, have associated risks. These may be broken down into several categories. For purposes of this discussion, I will consider the periopaerative risks as those that may occur during and immediately following surgery. Postoperative risks are those that may occur after the patient has been discharged. Furthermore, I will make a distinction between complications that are related to the surgical procedure and separate these from the risks associated with the use of the synthetic polypropylene mesh.

Looking at the TVT, TVT-O, TVT Exact and TVT Abbrevo, there have been many studies that have reported on complications. Bladder perforations are reported in as

many as 5.5% of the retropubic TVTs but do not occur with the transobturator procedures. Unlike bladder injuries that might occur with the MMK, Burch or PVS, those associated with TVT do not require repair. They are easily identified with cystoscopy, an integral part of every TVT, and treated by simply removing the offending trocar. The injury to the bladder is no more than a perforation with a large bore needle and it is self-sealing.

Urethral injuries have been reported at less than 1% (Daneshgari 2008). Bowel injuries have been reported only with the TVT at 0.34%. Hemorrhage requiring transfusion occurs less than 2% of the time (Shah 2012). Vaginal mesh exposure occurs between 1-3% (Schimpf, 2014; Cochrane 2015).

In 2015, Welk reported in JAMA on 59,887 patients who had MUS. 2.2% of them had repeat surgery for complications and the 10-year cumulative rate of complications was 3% (Schimpf 2014).

These statistics mean little when looked at by themselves. More important is how they compare with the complications of the two other most effective procedures, MMK/Burch and PVS. The Society of Gynecologic Surgeons (SGS) performed a systematic review comparing MUS with both the Burch and the PVS. It found that when compared with the Burch, MUS had a lower rate of adverse events including blood loss, postoperative pain, bowel injury, wound infections, DVT, and hematomas. In addition MUS had shorter operating times and hospital stays. When compared with PVS, MUS had fewer adverse events including lower blood loss, transfusion, wound infection, urinary retention, overactive bladder, DVT, and also had shorter operating time and hospital stay. The PVS had a lower rate of UTI and vaginal perforations. The MUS procedures also had a better subjective cure rate (Schimpf 2014).

Urinary retention may follow any incontinence procedure. Oliphant (2009) reported retention followed non-mesh slings 19% of the time compared with 13% following

mesh MUS. In the SGS systematic review, urinary retention lasting longer than 6 weeks was reported at a rate of 2.7% following MUS compared with 7.6% following Burch, and 7.5% following PVS.

Vaginal pain, pelvic pain and dyspareunia may occur following any pelvic surgery. In fact, these complaints are associated with hysterectomy in 20% of cases (Adelmonem 2010). Pain and sexual dysfunction also occur at higher rates following a Burch procedure compared to MUSs (AUA 2012 Update to the SUI Guidellines). In fact, the SISTEr trial found that 47% of Burch patients experienced some adverse event (Albo 2007).

In the TOMUS trial comparing TVT with TVT-O, sexual function actually improved and dyspareunia decreased over a 2-year span from 38% to 27%. Dyspareunia is less following MUS compared with both the Burch and PVS (Schimpf 2014).

Thigh and groin pain is higher following the TVT-O and TVT Abbrevo because the trocar and mesh pass through some of the adductor muscles of the groin, but studies reveal that this pain usually resolves with time and the administration of NSAIDs. In fact, long term TVT-O studies reveal little to no long-term thigh or groin pain.

Taken as a whole the rate of dyspareunia, pelvic pain and vaginal pain following MUS procedures is very low (Tommaselli 2015).

Urinary tract infection (UTI) is a risk following any incontinence surgery and is commonly known to be elevated in post-menopausal women—especially those experiencing urological problems (Haylen 2009). Results of the SISTEr and the TOMUS trials revealed that UTI was lower following TVT (17%) and TVT-O (11%) than following PVS (48%) or Burch (32%) (Albo 2007, Albo 2012).

There are several complications unique to the MUS procedures as a function of the use of permanent synthetic mesh. These generally fall under several headings; mesh

exposure and dyspareunia secondary to superficial placement of the sling, Both of these are relatively uncommon. Collective data from HMOs in the United States reported a nine-year rate of mesh revision or removal of 3.7% (Jonsson 2013).

Mesh exposures have a multifactorial etiology. Vaginal wound separations are not uncommon in vaginal surgery whether or not mesh is used, and certainly all vaginal surgeons are very familiar with this complication. Obesity, smoking status, diabetes, hematoma formation, and vaginal intercourse prior to healing of the incision site are all risk factors. There are times that exposures result from the sling being placed too superficially under the vaginal surface. When positioned under the full thickness of the vaginal wall, it should not be easily palpable by an examining physician and should not be associated with pain.

It has been suggested that infection plays a role in exposure, but I am not aware of any significant data to support this. In my experience, I have never seen a case in which infection was the cause for an exposure.

In any event, if complications do occur, whether secondary to voiding dysfunction, exposure or pain unrelated to exposure, they are easy to resolve by either revising the incision or removing part of the sling. Technically, this is easy to do through the same small suburethral incision. It has been extremely unusual that any mesh-related problems have not been totally resolved following such a procedure. Although recurrent SUI may occur following sling removal, it frequently does not because there is residual scar tissue left behind that may provide continued satisfactory support of the midurethra.

<u>What Mesh Is Used With TVT And Why ?</u>

Synthetic mesh products have been used in surgery for many years. Within the field of pelvic floor surgery, this use was prompted by a desire to find a substitute for autologous fascia in the PVS procedure since the harvesting of fascia from a patient

was associated with increased morbidity in the form of wound complications. Dr. TeLinde reported using a Mersilene sling in 1962. In 1966, Dr. Ridley reported on complications with Mersilene including erosion into the bladder.

In 1996, Dr. Norris described their experience with multiple mesh materials including Marlex, Silastic, Mersilene, Teflon, and GoreTex and the complications associated with use of these materials. Suffice it to say that synthetic mesh materials and the potential complications associated with their use were well known within the field of gynecology and pelvic floor surgery long before the TVT was introduced.

The quest for finding a synthetic graft material with low risk of complications continued. In 1997, Amid categorized synthetic materials used in hernia repair based on a number of attributes. He created a list with four subtypes. Type 1 is characterized by being made from knitted monofilament strands with pore size exceeding 75 microns. He also described why polypropylene was superior to other synthetic products stating that it is completely inert, resists infection and sinus tract formation, has rapid fibrinous fixation, becomes completely incorporated into the host tissue, and in case of infection does not have to be removed. The prolene mesh used with TVT, TVT Exact, TVT-O and TVT Abbrevo is Amid Type 1, a large pore lightweight mesh (AUGS/SUFU 2014, 2016 and 2018).

In 2003, Dietz compared the properties of eight different synthetic implant materials and found that the polypropylene mesh used in the TVT had a very low erosion rate.

In 2008, Moalli's group compared the TVT/TVT-O mesh with the mesh used in five other MUS products. TVT had the largest pore size. They opined that erosions were lowest with the TVT because of the superior biomechanical properties.

In 2015, the Cochrane review on midurethral slings stated the type 1 polypropylene mesh was the most biocompatible synthetic material for use in the pelvic floor. In

addition, it is the favored graft material for hernia repairs and has significantly enhanced success of hernia surgery (Cobb 2005).

In the initial TVT trials using polypropylene mesh, Dr. Ulmsten found no unacceptable rates of infection, rejection or impaired healing (Ulmsten 1998). Prolene mesh was chosen by Dr. Ulmsten due to its superior biocompatibility and tissue integration (Petros 2014). Another study based on biopsies 2 years following implantation found no evidence of host tissue reaction (Falconer 2001).

TVT-O and TVT Abbrevo

TVT-O is comprised of the same Prolene mesh used in TVT. Cleared by the FDA in 2003 and launched in 2004, TVT-O has demonstrated long term efficacy and safety similar to that of TVT. Like TVT, numerous long term studies support the safety and efficacy of TVT-O (Groutz 2011; Athanasiou 2014; Laurikainen 2014; Cheng 2012; Angioli 2010; Liapis 2010; Serati 2013; Abdel-Fattah 2016; Tammaa 2017; Roy 2017). Multiple RCTs and systematic reviews/meta-analyses also support TVT-O's similar safety and efficacy to TVT (Cochrane 2015; Schimpf 2014; Tommaselli 2015). Complications of leg/thigh/groin pain are relatively low and almost always confined to the immediate post-operative period, after which they resolve. In fact, the long term studies cited above are remarkable for the lack of long term complaints of leg, thigh or groin pain.

Like the TVT-O, TVT Abbrevo is a transobturator sling made of the exact same lightweight, macroporous Prolene mesh as TVT and TVT-O. First cleared and sold in 2010, it's similar safety and efficacy compared to TVT-O is confirmed in multiple clinical studies and RCTs. Developed by Professor Jean de Leval and Dr. David Waltregny, TVT Abbrevo consists of a 12 cm Prolene sling covered by a clear sheath. It's accompanied by two Helical Passer Sheaths, a Winged Guide and a centering loop to assist in the placement of the mesh. The launch of TVT Abbrevo was supported by adequate clinical data to demonstrate it's safety, efficacy, and

similarity to TVT-O (Hinoul cadaver study (2011); de Leval 2011). Dr. de Leval's 2011 RCT found that there was no statistical difference in terms of cure rates between TVT-O and TVT Abbrevo and that between the two arms of the 175 patient study, only one mesh exposure was noted. The three year data published on this study found an overall subjective cure rate of 84.3% and no meaningful difference between the two products (de Leval 2012). Other studies and RCTs have found TVT Abbrevo to be safe and effective (Tommaselli 2012 and 2016; Dati 2012; Narang 2013; Capobianco 2014; Kurien 2014; Shaw 2015).

Endorsement by multiple professional societies

As a result of the efficacy and safety of the TVT, TVT-O and TVT Abbrevo, numerous professional organizations as well as the FDA have endorsed the use of polypropylene midurethral slings:

> AUGS-SUFU position statement, 2014
>
> "As the knitted form, Polypropylene mesh is the consensus material as a graft augmentation layer for hernia repairs in a number of areas of the human body and has significantly and favorably impacted the field of hernia surgery. As an implant for the surgical treatment of SUI, macroporous, monofilament polypropylene has demonstrated long-term durability, safety, and efficacy for up to 17 years."
>
> "Polypropylene mesh midurethral slings are the standard of care for the surgical treatment of SUI and represent a great advance in the treatment of this condition for our patients. Since the publication of numerous level one randomized comparative trials, the MUS has become the most common surgical procedure for the treatment of SUI in the US and the developed world. This procedure has essentially replaced open and transvaginal suspension surgeries for uncomplicated SUI. . . . Full-length midurethral slings, both retropubic and transobturator, have been extensively studied, are safe and effective relative to other treatment options and remain the leading treatment option and current

gold standard for stress incontinence surgery. Over 3 million MUS have been placed worldwide and a recent survey indicates that these procedures are used by> 99% of AUGS members."

"One of the unintended consequences of this polypropylene mesh controversy has been to keep women from receiving any treatment for SUI. This procedure is probably the most important advancement in the treatment of stress urinary incontinence in the last 50 years and has the full support of our organizations which are dedicated to improving the lives of women with urinary incontinence." This statement was updated in 2016 and again in 2018.

ACOG/AUGS Practice Bulletin, 2015

"Although controversy exists about the role of synthetic mesh used in the vaginal repair of pelvic organ prolapse, there are substantial safety and efficacy data that support the role of synthetic mesh midurethral slings as a primary surgical treatment option for stress urinary incontinence in women. For this reason, and to clarify uncertainty for patients and practitioners, the American Urogynecologic Society and the Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction published a position statement recognizing polypropylene mesh midurethral slings as the 'standard of care' in the surgical treatment of stress urinary incontinence."

AUA Position Statement, 2011

"Multiple case series and randomized controlled trials attest to the efficacy of synthetic polypropylene mesh slings at 5–10 years. This efficacy is equivalent or superior to other surgical techniques. There is no significant increase in adverse events observed over this period of follow-up. Based on these data, the AUA Guideline for the Surgical Management of Stress Urinary Incontinence (2009) concluded that synthetic slings are an appropriate treatment choice for women with stress incontinence, with similar efficacy but less morbidity than conventional non-mesh sling techniques."

ICS Fact Sheets, 2013

"Worldwide, midurethral slings comprised of synthetic mesh have become

the treatment of choice for SUI. Long-term data are robust and demonstrate durable efficacy with a very low complication rate, particularly in experienced hands. Various techniques for sling placement and different meshes are employed according to physician preference, but all appear to be equally effective."

EAU Guidelines: Eur Urol. 2012

"There has been a rapid adoption of midurethral synthetic sling insertion as the first-line surgical option for SUI because it is effective, it is less invasive, and patients recover more quickly."

FDA, 2013

"Mesh sling procedures are currently the most common type of surgery performed to correct SUI. Based on industry estimates, there were approximately 250,000 of these procedures performed in 2010."

"The safety and effectiveness of multi-incision slings is well-established in clinical trials that followed patients for up to one-year."

FDA Executive Summary, 2011

"The Burch has a long history, but its popularity has declined over the past two decades with the introduction of less invasive procedures" and "the pubovaginal sling procedures using biologic graft material (often autologous fascia) similarly have declined in popularity."

"The anterior repair with Kelly plication to correct SUI in the presence of a cystocele and bladder neck needle suspension is rarely performed currently due to poor long-term outcomes."

FDA Executive Summary, 2011

"A substantial number of quality clinical trials, as well as systematic reviews, have been published for the first generation minimally invasive slings that provide evidence of safety and effectiveness of these devices."

"After considering all available data on both safety and effectiveness, and considering the risk/benefit profile, it appears that new premarket clinical trials are not warranted for minimally invasive slings for SUI unless the device has new features (e.g. new polymer or coating) that could affect

device performance."

AUA Position Statement, 2012

"Suburethral synthetic polypropylene mesh sling placement is the most common surgery currently performed for SUI. Extensive data exist to support the use of synthetic polypropylene mesh suburethral slings for the treatment of female SUI, with minimal morbidity compared with alternative surgeries. Advantages include shorter operative time/anesthetic need, reduced surgical pain, reduced hospitalization, and reduced voiding dysfunction. Mesh-related complications can occur following polypropylene sling placement, but the rate of these complications is acceptably low. Furthermore, it is important to recognize that many sling-related complications are not unique to mesh surgeries and are known to occur with non-mesh sling procedures as well. It is the AUA's opinion that any restriction of the use of synthetic polypropylene mesh suburethral slings would be a disservice to women who choose surgical correction of SUI."

"Multiple case series and randomized controlled trials attest to the efficacy of synthetic polypropylene mesh slings at 5–10 years. This efficacy is equivalent or superior to other surgical techniques. There is no significant increase in adverse events observed over this period of follow-up. Based on these data, the AUA Guideline for the Surgical Management of Stress Urinary Incontinence (2009) concluded that synthetic slings are an appropriate treatment choice for women with stress incontinence, with similar efficacy but less morbidity than conventional non-mesh sling techniques."

I agree with all these statements. Of note, following their public health notices of 2008 and 2011, the FDA conducted a systematic review of the medical literature and concluded in 2013 that full length MUSs like TVT and TVT-O and TVT Abbrevo are safe and effective based on the medical literature reflecting up to a 12 month follow-up. In an April 16, 2019 post on their web site, the FDA asserted that it's 2013 statement represented its "current thinking" on the safety and efficacy of MUSs

(https://www.fda.gov/medical-devices/urogynecologic-surgical-mesh-implants/fdas-activities-urogynecologic-surgical-mesh).

Instructions for Use

The instructions for use provided with TVT, TVT-O, TVT Abbrevo and TVT Exact were adequate and appropriately warned surgeons of any risks that were unique to those products. Plaintiff experts have alleged that all TVT IFUs are deficient. However, these claims are without merit. Risks pertaining to pelvic pain, dyspareunia, vaginal scarring, infection, re-operation and voiding dysfunction are commonly known basic elemental risks of vaginal surgery in general and have been known as such for decades. Pelvic floor surgeons understand and are familiar with these risks from their education, training, clinical experience and ongoing review of the medical literature. Importantly, these risks have been well reported in the medical literature and textbooks before TVT was first sold in 1998 (Moore 1955; Francis 1961; Williams 1962; Morgan 1970; Amias 1975; Stanton 1985; Galloway 1987; Haase 1988; Kahn 1997; Kholi 1998). In fact, mesh erosion/exposure is the only risk unique to mesh products and this risk is not only warned about in the TVT labeling, but has been well known as a basic elemental risk of mesh surgery for decades. In addition to the publicly available medical literature, Ethicon provided doctors like myself professional educational opportunities in which the risks and potential complication associated with MUS surgery was discussed. Professional education slide decks and the TVT Surgeons monograph (2000) also provided additional risk information to doctors.

What Other Adverse Claims Have Been Made About The Use Of Polypropylene Mesh?

There have been many allegations as to the harmful effects of midurethral slings and the polypropylene mesh used with these products.

"Roping" and "curling" of the mesh is said to occur frequently and, as a result, cause complications. All of the Ethicon MUS products that are the focus of this document have a plastic sheath that covers the mesh and is not removed until the sling has been positioned properly. By design, this serves two important purposes: preserving the architecture of the mesh before any tension is applied; and preventing exposure of the mesh to bacterial contamination. The mesh is implanted with the sheaths intact. Once the proper tensioning is established and the sheaths are removed, the surgeon may clearly see that the mesh has not stretched and, therefore not roped or curled.

One might then question whether the roping or curling might occur postoperatively once the sling is subjected to the increased intraabdominal pressures that occur with coughing of sneezing. In fact, as I mentioned in the section about insertion technique, the Velcro effect that occurs immediately upon removing the plastic sheaths makes it very difficult to move the mesh and deform it. Within two weeks there is tissue ingrowth into the pores. At that point, it can not change shape.

Examining the mesh in situations requiring explantation provides further evidence of this. I have had occasion to perform explants and observe the mesh in a number of these situations. There has been no evidence that the initial shape changed at all.

"Fragmenting" or fraying of mesh is another claim. This is thought to happen more frequently with mechanically cut as opposed to the laser cut products that were introduced later. According to the claim, small fragments or particles of mesh could detach and then cause harm by migrating to other parts of the body or inducing a cytotoxic or inflammatory host response.

Ethicon used mechanically cut mesh until 2007. After introducing the laser cut product, it continued to offer the mechanically cut mesh as well. Despite the claims by plaintiffs' experts about the harmful effects of ,fraying or particle loss, there is no scientific data to support it that I am aware of. Moreover, I have not seen these

alleged complaints in my extensive clinical experience. Nor have I seen mesh shrinkage or contraction in my practice. While it's been commonly known that scar tissue will act on a mesh graft to cause in some cases minimal amounts of shrinkage, this does not happen with MUSs in any clinically meaningful way. The mesh in the TVT products are well designed for tissue integration and any scar tissue formation that occurs following implantation. Long term follow-up studies and other studies support this opinion (Nilsson 2013).

Claims that either laser or mechanically cut mesh are defectively designed are also baseless. Claims that the cut of the mesh causes mesh erosion or complications are not supported by the medical literature or seen in my clinical experience. To my knowledge only one study has compared laser and mechanically cut mesh and in concluded that there is no clinically significant difference between the two (Rusavy 2017).

"Cytotoxicity" is another claim. A number of plaintiff expert witnesses have claimed that the polypropylene has a cytotoxic effect. By destroying the cell layer overlying the mesh, it is hypothesized that mesh exposure results. The weight of the scientific evidence contradicts this claim. The biocompatibility of Prolene has been well established since the FDA first cleared Prolene sutures for use a half century ago. Since then, Prolene has been used in practically every surgery in billions of patients. Moreover, professional societies around the planet have affirmed the biocompatibility of Prolene mesh for use in vaginal surgeries (see the 2018 AUGS/SUFU position statement which was also endorsed by ACOG).

If cytotoxicity is an inherent property of polypropylene, observations of resulting adverse events should be far more commonplace and should have become evident years before the TVT was introduced. Polypropylene has been used in the form of suture material for decades for surgery throughout the entire human body.

Plaintiff's claim that Prolene mesh degrades is also without merit. I'm aware of no medical literature that supports the conclusion that Prolene mesh degrades in any clinically meaningful way. Plaintiffs claim that Clave 2010 supports Prolene degradation is unsupported and does not demonstrate degradation. In fact, studies demonstrate just the opposite (Thames 2017) and that plaintiffs' claims that the Prolene fiber undergoes a "barking" barking process are without merit. AUGS/SUFU (2014 FAQ) has addressed the question of degradation and concluded the following:

"Does the MUS mesh made of polypropylene degrade over time?
Polypropylene is a stable and well-accepted biomaterial with a history of over five decades of use in mesh implants. In recent years, concerns regarding implanted polypropylene degradation have been raised as a result of very high-AUGS-SUFU FAQs by Providers on Mid-urethral Slings for SUI -2- magnification images that show portions of some explanted synthetic meshes with "cracked" surfaces. These surface changes were further hypothesized to lead to adverse clinical outcomes, though this is not supported by the extensive peer-reviewed literature related to polypropylene mesh repairs. Prospective studies have followed patients with implanted mid-urethral slings for 17 years and show excellent durability and safety of the procedure."

I agree with this statement.

"Chronic inflammatory reaction" is another charge made about mesh. Every foreign body creates some inflammatory response in the host. That is a normal, expected finding and one that is not harmful. Prolene mesh, like any biocompatible foreign body may illicit an acute or transient foreign body reaction upon initial implantation. To the extent the foreign body reaction continues in the long-term, it is of no clinical significance and does not result in complications like pain or mesh contraction. Additionally, studies have shown ideal tissue reaction with TVT (Falconer C. Int Urogyn J 2001). Infection is a risk of any surgery. The clinical literature regarding the infection rate of TVT mesh is very low. In fact, wound complications with TVT are less than that with non mesh repairs like Burch and the pubovaginal sling. (Schimpf, 2014).

"Carcinogenisis" or the risk that that polypropylene causes cancer is another claim.

No evidence is available that Prolene mesh is causes cancer. Reliable data do not show a risk of sarcoma or cancer. (Moalli P., Int Urogyn J 2014; King 2014; Linder 2016)

My first exposure to TVT came through a cadaver lab event sponsored by Ethicon and taught by physician users who were considered experts by the company. The quality of the instruction, both didactic and practical, was excellent. I attended the annual summit meetings sponsored by Ethicon for all of the preceptors. I looked forward to this gathering every year because I was so impressed with the quality of the physicians they had selected. As I mentioned earlier, the agenda was loosely set allowing discussion to proceed unhindered and in any direction the physician attendees wished to go to include discussion of all potential complications. These were exciting times for all of us as we were on the cusp of a revolutionary change in the treatment of SUI.

Plaintiffs' experts have alleged that a lighter weight or larger pore mesh would be a safer alternative design to the TVT family of products. These claims are without merit. I am aware of no scientific study or published piece of peer reviewed medical literature that supports this contention. In fact, the only study cited by plaintiffs' experts to support their contention that a lighter weight or partially absorbable mash would be a safer alternative to the TVT mesh is Okulu, 2014. This study however has many limitations and even found a mesh erosion in the Ultrapro arm of the study. Simply put there is no evidence to support the claim that a lighter weight or larger pore mesh would prevent or even significantly reduce potential complications following MUS surgery such as mesh exposure, pain or dyspareunia. In fact, Ethicon attempted to develop a lighter weight and partially absorbable mash in what was called project TOPA. This attempt however never advanced beyond cadaver lab testing in which every cadaver lab failed. Moreover, the FDA refused to clear this proposed partially absorbable, lighter weight mesh to treat SUI.

Summary

Stress urinary incontinence is a huge problem in our country and it imposes a tremendous physical, psychological, and economic burden on the millions of women who suffer from it. Prior to TVT and the MUS family of products, many women either refused or did not seek treatment because they were aware that it involved major surgery with a significant risk of failure and complications.

TVT and later, TVT-O, TVT Abbrevo and TVT Exact ushered in a revolutionary new era in treating this problem. Major surgery was substituted with minor, inpatient with outpatient, prolonged postoperative pain with minimal, a large abdominal incision with a hidden vaginal micro-incision. Even better, success, both subjective and objective, was as good as, and most of the times better than, the former operations that they quickly displaced from holding the title, "gold standard." These products have been a safe and effective standard of care treatment for SUI.

Furthermore, voluminous data was soon forthcoming proving that complication rates were lower whether one looked at infection, blood loss, voiding dysfunction, urinary retention, pain, dyspareunia, and damage to bowel, bladder or urethra with TVT, TVT-O, TVT Exact and TVT Abbrevo.

The safety of the mesh was never a serious concern in my mind as Prolene has been used for decades in the form of mesh or suture. It remains the most popular synthetic mesh used in surgery.

As a result of all of these factors including the thousands of peer-reviewed scientific articles, the opinions of many independent physicians who are widely acclaimed to be thought leaders in the field of urogynecology, and the numerous prestigious societies of my profession that have strongly endorsed MUS, I remain unswayed in the level of confidence that I have in all of these products: TVT, TVT-O, TVT Exact, and TVT Abbrevo.

Finally, I have accumulated a vast experience with TVT, TVT-O, TVT Exact, and TVT Abbrevo. I believe the benefit of these products clearly outweigh the risks. I believe they are invaluable to the enhancement of the quality of life of millions of women. I believe these products were state of the art when they were introduced and earned their "gold standard" rating. I believe they remain state of the art today.

I reserve the right to supplement or modify my expert opinion based on the discovery, disclosure and timely provision of new findings and the depositions of Plaintiffs' experts. I hold all of the above opinions to a reasonable degree of scientific and medical certainty.

Charles R. Hanes, II

Charles R. Hanes, II, MD
June 23, 2019

Charles Hanes

General Materials List
in Addition to Materials Referenced in Report

Charles Hanes Materials List

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Charles Hanes Materials List

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Clinical Evaluation Report - Gynemesh PS by Piet Hinoul - April 26, 2013
ETH.MESH.00012009-089 - TVM Prospective Data (French Trial) - Exhibit 522
ETH.MESH.00013529-534 - Prolift+M IFU
ETH.MESH.00018382 - Powerpoint GYNECARE GYNEMESH* PS Nonabsorbable PROLENE* Soft Mesh in the Treatment of Pelvic Organ Prolapse
ETH.MESH.00159266-369 - Gynemesh PS, Prolene Soft Mesh in the treatment of POP - Pelvic Floor Surgery and Anatomic Dissection Lab
ETH.MESH.00167104 - 2006 TVT Laser Cut Clinical Expert Report
ETH.MESH.00295355 (TVTE-338-10-7.12) - 2010 TVT-Exact Prof Ed
ETH.MESH.00308094 (2629_2006-07-12) - 2006 TVT-Secur
ETH.MESH.00354732 (TVTA-088-11-2.13) - 2011 TVT-Abbrevo
ETH.MESH.00369995 (2008-570) - 2008 TVT Family of Products Prof Ed
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ETH.MESH.00370421 (TVTO_0113-09-8.11) - TVT-O FDA Public Health Notice
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ETH.MESH.00395374-380 - 2001 June 22; Scientific Advisory Chicago Meeting re POP mesh includes Prolene Soft
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ETH.MESH.00520649-722 - 2006 US TVM 12 Month Clinical Report
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ETH.MESH.00747864-874 - Gynemesh PS DDSA Rev. 2
ETH.MESH.00993273 (2091_2006-02-01) - 2006 TVT-O Summit Presentation by Raders and Lucente
ETH.MESH.01128679-98 (TVTS007) - 2007 TVT-Secur Procedural Steps
ETH.MESH.01222075 - 2006 Kammerer Memo
ETH.MESH.01261962 (2005-1819) - TVT-O Summit by Raders, Rogers, Lucente
ETH.MESH.02219584 - 2010 Scion PA Unmet Needs Exploratory Research
ETH.MESH.02330776 (TVTO-384-10-8.12) - TVT-O
ETH.MESH.02341398-410 - Prosima IFU
ETH.MESH.02341454-459 - Prolift 2007-2009 IFU
ETH.MESH.02341522-527 - Prolift 2005-2007 IFU
ETH.MESH.02341658-664 - Prolift 2010-2012 IFU - Text Searchable
ETH.MESH.02341734-740 - Prolift 2009-2010 IFU
ETH.MESH.02342097 Prolene Soft IFU
ETH.MESH.02342101 Prolene Soft IFU
ETH.MESH.02342102 Prolene Mesh IFU

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ETH.MESH.02342152-54 Prolene Mesh IFU
ETH.MESH.02342194-196 - Gynecare Gynemesh PS IFU (English Only)
ETH.MESH.02342218-220 - Gynecare Gynemesh PS IFU (English Only)
ETH.MESH.02342250-252 - Gynecare Gynemesh PS IFU (English Only)
ETH.MESH.02342278-279 - Gynecare Gynemesh PS IFU (English Only)
ETH.MESH.02603812-821 - Dissection Techniques in Transvaginal Pelvic Organ Prolapse Repair with Synthetic Mesh
ETH.MESH.02616825-27 Prolene Soft IFU
ETH.MESH.03458123-38 - TVT Patient Brochure 3.19.08
ETH.MESH.03460813-853 - Prolift Surgeons Resource Monograph 2007
ETH.MESH.0370392 (3914_2007-08-22) - 2007 TVT-Secur
ETH.MESH.03715787-793 - Gynemesh PS CER (2002) - Weisberg
ETH.MESH.03751819 (2009-473) - 2009 The Science of What's Left Behind
ETH.MESH.03905968-975 - Prolift 2005 Brochure
ETH.MESH.03905976-991 - Prolift 2006 Brochure
ETH.MESH.03906001-020 - Prosima and Prolift+M
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ETH.MESH.04046302 (TVT and TVT-O)(2005-1117)
ETH.MESH.04079609 (TVTA-401-10-8.12) - 2010 TVT-Abbrevo
ETH.MESH.04202101 (2008-448)
ETH.MESH.05222686-88 - TVT IFU (4th version) 4.7.06-10.7.08
ETH.MESH.05320909 (2008-135)(38 slides summit) - 2008 TVT-Secur
ETH.MESH.05795421 (2001-227) - 2001 TVT Prof Ed
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ETH.MESH.07201006 - Prolift Prof Ed 2007 Slide Deck
ETH.MESH.07246690-19 - Study Report - A systematic review of patient-years of experience in prospective randomized controlled trials (RCTs) in incontinence.
ETH.MESH.08003279-94 - TVT Patient Brochure 12.10.08
ETH.MESH.08117473 - 2012 TVT-Exact Updated Prof Ed Slide Deck w Production Cover
ETH.MESH.08156958 (2002-310) - 2002 TVT Advanced Users Forum Presentation
ETH.MESH.08307644-45 - 4.05.2013 - Email from P. Hinoul to G. Callen re: RCT data (with attachments).
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ETH.MESH.09744840-45 - TVT Patient Brochure 2.14.13
ETH.MESH.10027307-28 - Surgeon's Resource Monograph
ETH.MESH.10686760-771 - Gynemesh PS aFMEA 2013
ETH.MESH.10686833-852 - Risk Management Report (RMR) for Gynemesh PS 2013
ETH.MESH.11543641 - Powerpoint GYNECARE GYNEMESH* PS Nonabsorbable PROLENE* Soft Mesh Awareness Module
ETH.MESH.11543719 - Robinson Gynemesh PS Presentation Awareness Module 4.7.04
ETH.MESH.22625140-45 - MDD CAPA # CAPA-003474
ETH.MESH.22631022-29 - Response to Section 39 Request, D-1, 1-1002
ETH-02288-289 - Gangam N. Retroperitoneal hemorrhage after a vaginal mesh prolapse procedure. Obstet Gynecol 2007; 110: 463-4
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Gynecare TVT IFU changes redlined, D-6, 1-20
Gynemesh PS 510k Approval File [FDA]
Gynemesh PS white paper - Early Clinical Experience
K013718 GYNEMESH PS (Ethicon) Corrected SE Letter (07-Nov-2012)
May 2010 CER for Gynemesh PS signed by David Robinson
PS120046 A2 - 7.9.12 FDA Response to Ethicon re Gynemesh PS
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Company Witness Depositions

Hinoul, Piet - 01.15.2014 Deposition Testimony
Weisberg, Martin - 11.13.2015 Deposition Testimony

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Other Materials

2008 FDA Public Health Notification: Serious complications associated with transvaginal placment of surgical mesh in repair of pelvic organ prolapse and stress urinary incontinence.
2011 IUGA Patient Brochure - Vaginal Repair with Mesh Patient Brochure
2012 ABOG and ABU Guide to Learning in Female Pelvic Medicine and Recontructive Surgery.
2012 ABOG Guide to Learning in Female Pelvic Medicine and Reconstructive Surgery
2012 AUA Guidelines - Guideline for the Surgical Management of Female Stress Urinary Incontinence: 2009 Update - Appendices A11 and A16
2013 AUA Position Statement on the Use of Vaginal Mesh for the Surgical Treatment of Stress Urinary Incontinence.
2013 AUGS Guidelines for Privileging and Credentialing Physicians for Sacrocolpopexy for Pelvic Organ Prolapse
2013 FDA Statement regarding Considerations about Surgical Mesh for SUI
2014 IUGA Position Statement on Mid-Urethral Slings for Stress Urinary Incontinence
2015 ACOG Practice Bulletin #155 Summary - Urinary Incontinence in Women, 1120-1122
2016 AUGS, SUFU, ACOG, SGS, AAGL, NAFC,WHF, Position Statement - Mesh Midurethral Slings for Stress Urinary Incontinence
2016 August - ICS IUGA ACOG AUGS AUA SUFU - Groups reaffirm position on use of vaginal mesh for surgical treatment of stress urinary incontinence
2016 IUGA Patient Brochure on Midurethral Sling Procedures for Stress Incontinence
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2017 AUA, SUFU Guideline - Surgical Treatment of Female Stress Urinary Incontinence, 1-33
2018 AUGS, SUFU, AAGL, ACOG, NAFC, SGS, Position Statement - Mesh Midurethrethral Slings for Stress Urinary Incontinence
2018 July - IUGA Global Statement in support of MUS for SUI
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ACGME Program Requirements for Graduate Medical Education in Female Pelvic Medicine and Reconstructive Surgery
ACOG Practice Bulletin Summary Urinary Incontinence in Women. Replaces Practice Bulletin Number 63, June 2005. 2015; 126(5)
American Urogynecologic Society Board of Directors. Position statement on restriction of surgical options for pelvic floor disorders: the American Urogynecologic Society Board of Directors. Female Pelvic Med Reconstr Surg. 2013 Jul-Aug; 19(4): 199-201
AUA. Position Statement on the Use of Vaginal Mesh for the Repair of Pelvic Organ Prolapse. November 2011; reaffirmed October 2016 and October 2018
AUGS Residency Guidelines
AUGS Resident Learning Objectives
AUGS/SUFU Mesh Midurethral slings for stress urinary incontinence. 2014, Updated 2016.
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MDL Wave Cases

Expert Reports
Blaivas, Jerry (Prolift General) - 01.17.2017
Blaivas, Jerry (TVT Abbrevo General) - 01.17.2017
Blaivas, Jerry (TVT Exact General) - 01.17.2017
Blaivas, Jerry (TVT-O General) - 01.17.2017
Elliott, Daniel (Prolift General)
Elliott, Daniel (TVT-O General) - 05.22.2017
Guelcher, Scott (General)
Guelcher, Scott (Wave 5 General)
Iakovlev, Vladimir (General) - 01.29.2016
Iakovlev, Vladimir (Wave 10 General) - 02.20.2019
Iakovlev, Vladimir (Wave 10 General) - 02.20.2019
Klinge, Uwe (POP General) - 11.17.2015
Klinge, Uwe (TVT General) - 11.16.2015
Margolis, Michael (TVT General) - 05.21.2017
Mays, Jimmy (General) - 05.22.2017
MDL Wave 9 and 10 Plaintiff General Reports
Ostergard, Donald (General) - 05.19.2017
Pence, Peggy (General TVT) - 10.14.2013
Pence, Peggy (General TVT-O) - 7.17.2014
Pence, Peggy (Notice of Adoption of Prior Reports) - 2.01.2016
Pence, Peggy (Prolift General) - 07.17.2014
Pence, Peggy (Supplemental General TVT & TVT-O) - 3.2.2016
Pence, Peggy (Supplemental General TVT-O) - 4.24.2015
Priddy, Duane (General)
Rosenzweig, Bruce (Prosima General) - 05.22.2017
Rosenzweig, Bruce (TVT Abbrevo General) - 05.22.2017
Rosenzweig, Bruce (TVT Exact General) - 05.22.2017
Rosenzweig, Bruce (TVT General) - 05.22.2017
Rosenzweig, Bruce (TVT General) - 06.09.2014
Rosenzweig, Bruce (TVT General) - 08.24.2015
Rosenzweig, Bruce (TVT General) - 10.14.2013
Rosenzweig, Bruce (TVT Supplemental General) - 01.06.2017
Rosenzweig, Bruce (TVT, TVT-O Notice of Adoption of Prior Reports) - 12.15.2015
Rosenzweig, Bruce (TVT-O General) - 02.21.2014
Rosenzweig, Bruce (TVT-O General) - 04.24.2015
Rosenzweig, Bruce (TVT-O General) - 05.22.2017
Shull, Bob (Prolift/Prolift +M General) - 02.01.2016
Zipper, Ralph (Prolift General) - 01.31.2016
Zipper, Ralph (TVT-S General) - 07.27.2017

CURRICULUM VITAE

Charles R. Hanes II, M.D.

BUSINESS ADDRESS:

Urogynecology of Southern Alabama
3 Mobile Infirmary Circle
Suite 401
Mobile, AL 36607

PROFESSIONAL LICENSURE:

Alabama Medical Licensure Commission 2004
License # 00008180

EDUCATION:

Vanderbilt University
Nashville, Tennessee 1963-1967

Tulane University Medical School
New Orleans, Louisiana 1967-1971

POSTGRADUATE TRAINING:

Vanderbilt University - Nashville, Tennessee
General Surgery 1971-1973
Emory University - Atlanta, Georgia
Residency, Ob-Gyn 1975-1978

POSTGRADUATE COURSES:

Update Pelvic and Vaginal Surgery 1998
American Urogynecology Advanced Pelvic Anatomy 1998
American Urogynecology Society Pelvic Surgery 1998
Advanced Pelvic Surgery 1999
CITI Course - Protection of Human Research Subjects, Principle Investigator Training 2004

CERTIFICATIONS:

American Board of Obstetrics and Gynecology - Voluntary Annual Recertification 1998-Present
Board certification - Female pelvic medicine and reconstructive surgery 2013-Present

PROFESSIONAL EXPERIENCE:

Private Practice, Ob-Gyn, Mobile, AL 1979-2000
Medical Director, The Continence Center Of Mobile
Mobile Ob-Gyn, P.C. 2001-2007
President Providence Hosp. Med. Staff 1990-1992
Director, Urogyneclogy of Southern Alabama 2007-present
Clinical Adjunct Assistant Professor, Dept. Ob-Gyn, Univ. of South Alabama 2003-present

PROFESSIONAL EXPERIENCE CONTINUED:

Preceptor for Ethicon Women's Health and Urology
Medical Staff - Providence Hospital, Springhill Medical Center, Mobile Infirmary Medical Center, The University of South Alabama
Private Practice-Birmingham, Alabama 1978-1979

MILITARY SERVICE: General Medical Officer U.S. Army 1973-1975

PROFESSIONAL ORGANIZATIONS:

Fellow, American College of Obstetrics & Gynecology 1981-present
Member of American Urogynecology Society 1997-Present
Mobile County Medical Society 1979-Present
Medical Association of The State of Alabama 1978-Present
Member Society Gynecologic Surgeons 2005-Present

OTHER: The Best Doctors in America 2003-present

VOLUNTEER/COMMUNITY EXPERIENCE:

Volunteer Physician, Victory Health Clinic
Medical Director, Sav-A-Life

PUBLICATIONS:

29th Annual Scientific Meeting Society of Gynecologic Surgeons, 2003
"TVT Pilot Study- A modified Technique to Improve Voiding Dysfunction",
C.R. Hanes II, M.D.

Journal of Pelvic Medicine & Surgery, Volume 11, Number 2, pg. 72, March/April 2005:
"Enhanced Preservation of Vaginal Length and Vault Support: A Byproduct of Anterior Compartment Repair Using a Synthetic Mesh Graft",
C.R. Hanes II, M.D. and M.S. Mulekar PhD,
Providence Hospital & Mobile Ob-Gyn, P.C., Mobile, AL

C.R Hanes, F.H. Long. Vaginal Sacral Colpopexy. Female Pelvic Med Reconstr Surg. 2009; 15(2):66.

Charles R. Hanes II. Natural Orifice Sacral Colpopexy. OBG Manag. November 2016; 28(11).

C.R. Hanes. Vaginal Sacral Colpopexy: A Natural Orifice Approach To A Gold Standard Procedure. Female Pelvic Med Reconstr Surg. 2017; 23(5), 875.

CR Hanes, II. Vaginal Sacral Colpopexy: A Natural Orifice Approach To A Gold Standard Procedure. JMIG. 2018; 25(1), 47-52.

PRESENTATIONS:

03/25/2004 - Grand Rounds - University of South Alabama Medical Center, Department of Ob-Gyn, Mobile, AL - "Paravaginal Defects Associated with Vaginal Vault Prolapse: Do they always need to be repaired?"

04/29/2004 - Mobile Bay Ob-Gyn Society, Mobile, AL - "The Surgical Management of Female Stress Urinary Incontinence"

31st Annual Scientific Meeting Society of Gynecologic Surgeons Meeting, 2005
"Enhanced Preservation of Vaginal Length and Vault Support: A Byproduct of Anterior Compartment Repair Using a Synthetic Mesh Graft"

2014 Joint Meeting of the Alabama and Mississippi Section ACOG, 5/8/14
"Vaginal Sacral Colpopexy"

41st Annual Scientific Meeting Society of Gynecologic Surgeons Meeting, 03/24/2015
Academic Roundtable, "Natural Orifice Sacral Colpopexy

10/15/2015 – American Urogynecologic Society Meeting - Academic Roundtable, "Natural Orifice Sacral Colpopexy

26th University of South Alabama Obstetrics and Gynecology Conference, 4/20/17
"Apical Suspension: The Foundation for Success and Durability in Pelvic Reconstructive Surgery"

POSTER PRESENTATIONS:

35th Annual Scientific Meeting Society of Gynecologic Surgeons, 3/30/2009:
"Vaginal Sacral Colpoopexy",
C.R. Hanes II, M.D., F. H. Long, M.D., M.S. Mulekar, PhD

42nd Annual Scientific Meeting Society of Gynecologic Surgeons Meeting, Palm Springs, CA, April, 2016. Natural Orifice Sacral Colpopexy

44th AAGL Global Congress on Minimally Invasive Gynecology, 11/15/15
Virtual Poster, "Natural Orifice Sacral Colpopexy: A New Approach To A Time-Honored Procedure"

VIDEO PRESENTATIONS:

44th AAGL Global Congress on Minimally Invasive Gynecology, 11/15/15
"Natural Orifice Sacral Colpopexy"

42nd Annual Scientific Meeting Society of Gynecologic Surgeons, April 2016
"Natural Orifice Sacral Colpopexy"
C.R. Hanes II, M.D.

RESEARCH EXPERIENCE:

Principle Investigator:

"TVT- A Modified Technique to Improve Voiding Dysfunction", C.R. Hanes, II

"Anterior and Apical Compartment Repair Using a Single Piece of Graft in the Anterior Vaginal Wall - A Descriptive Study" Gynecare

Open-Label, Quality of Life, Post Marketing Trial, Comparing Detrol vs. Ditropan 5 mg. and Ditropan 10 mg. Pharmacia

A Phase 4 Open-Label "Multicenter Assessment of Transdermal Therapy in Overactive Bladder with Oxybutynin TDS (Oxytrol) MATRIX", Watson Laboratories

"TVT and TVTO: A Comparison of Postoperative Voiding Dysfunction. A Comparative Study to show that the TVTO procedure has a lower incidence of voiding dysfunction than the TVT procedure when performed with identical tensioning techniques." Gynecare

Open-Label Phase 4 "SECURE: SANCTURA Study to Evaluate Control of Urinary Systems Resulting From Overactive Bladder" Odyssey Pharmaceuticals, Inc.